

Amendments to the Claims

1. (Presently amended) An abuse-resistant controlled-release pharmaceutical composition, comprising microspheres comprising water insoluble matrix material and containing discrete particles of a pharmaceutically effective amount of an active water soluble compound capable of abuse, wherein said discrete particles (1) comprise micronized particles of said active water soluble compound having surfaces that are wetted with a coating of said water insoluble matrix material that is insoluble in water, and (2) are distributed throughout said microsphere within a matrix of comprising said coating water insoluble matrix material in a; wherein said matrix is elastic and present in an abuse-reducing amount such that and wherein crushing, compressing, fracturing, tumbling, rolling, or milling of said composition including said microspheres said matrix before coming in contact with water an aqueous environment increases the aqueous dissolution of said active water soluble compound in said composition-microspheres by less than about 15% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said active water soluble compound thereafter.
- 2 to 3. Cancelled.
4. (Previously presented) An abuse-resistant composition according to claim 1 wherein said matrix material is non-erodable at pH less than about 6.
5. (Original) An abuse-resistant composition according to claim 4 wherein said matrix material is erodable in the presence of bile salts and lipase.
6. Cancelled.
7. (Original) An abuse-resistant composition according to claim 1 wherein said compound is a narcotic.
8. Cancelled.

9. (Previously presented) An abuse-resistant composition according to claim 1 wherein crushing said matrix before contacting with water increases the aqueous dissolution of active water soluble compound in said composition by less than about 10% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said active water soluble compound thereafter.
10. Cancelled.
11. (Original) An abuse-resistant controlled-release pharmaceutical composition according to claim 1 for administration to a subject in need thereof from once to four times a day.
12. (Withdrawn) A method for the preparation of an sustained release pharmaceutical composition having a reduced potential for abuse, comprising:
  - providing a pharmaceutically active compound capable of inducing in a subject a reaction that is physiologically or psychologically addictive if administered in an immediate release dosage form;
  - applying a pressure force to a mixture comprising particles of said compound and a water insoluble material thereby resulting in surface coated particles; and
  - incorporating said surface coated particles into a pharmaceutical composition that when subjected to stress does not increase substantially the immediate release of said compound in an aqueous environment.
13. (Withdrawn) A method according to claim 12 wherein said force is applied to a dispersion of said particles in a flowable medium comprising said material.
14. (Withdrawn) A method according to claim 13 wherein said force is an abrupt pressure force.
15. (Withdrawn) A method according to claim 13 wherein said force is an ultrasonic force.

16. (Withdrawn) A method according to claim 13 wherein said force is piston generated shock wave.
17. (Withdrawn) A method according to claim 13 wherein said particles are micronized.
18. (Withdrawn) A method according to claim 17 wherein said particles have a mean particle size of less than about ten microns.
19. (Withdrawn) A method according to claim 13 wherein said material comprises a polymorphic wax.
20. (Withdrawn) A method according to claim 19 wherein said wax comprises a hydrogenated vegetable wax, a tri-, di- or mono-glyceride, or a mixture thereof.
21. (Withdrawn) A method according to claim 20 wherein said material comprises a polymeric material that is water insoluble, and erodable in the intestinal tract at pH greater than about 6.
22. (Withdrawn) A method according to claim 13 further comprising solidifying said dispersion into microspheres.
23. (Withdrawn) A method according to claim 12 wherein the application of mechanical stress to said composition modifies the aqueous dissolution of said compound by an increase of less than about 15% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said composition thereafter.
24. (Original) A dosage form according to claim 7 wherein said narcotic is selected from the group consisting of fentanyl, sufentanil, carfentanil, lofentanil, alfentanil, hydromorphone, oxycodone, hydroxycodone, propoxyphene, pentazocine, methadone, tilidine, butorphanol, buprenorphine, levorphanol, codeine, oxymorphone, meperidine, dihydrocodeinone and cocaine.

25. (Presently amended) An abuse-resistant controlled release pharmaceutical controlled release composition according to claim 1, wherein the surfaces of said particles of active water soluble compound are wetted with said coating material by applying a pressure-pulse-is applied to a dispersion of said particles active water soluble compound particles in a water insoluble fluid matrix ~~flowable mixture~~ of said coating material, thereby forming a flowable dispersion of said discrete particles in said water insoluble fluid matrix, and wherein said microspheres are formed by spraying said flowable dispersion of said discrete particles and said active water soluble compound to form a pressure-treated matrix into a chilling zone maintained at a temperature below the solidification temperature of said coating material.
26. (Cancelled).